REMARKS

Notwithstanding the indications in the Office Action summary, the Office Action of March 19, 2009, presents the examination of claims 67, 73-76, 255 and 278. Remaining claims 1-66, 68-72, 77-254, 256-277 and 279-294, directed to non-elected subject matter, have been canceled previously or are canceled in this paper.

Rejections under 35 U.S.C. § 112, first paragraph

Claims 75 and 76 stand rejected under 35 U.S.C. § 112, first paragraph, for alleged failure of the specification to provide enabling disclosure of the full scope of the claimed invention. The Examiner is requiring deposit of the virus HPIV3 JS cp45 under the terms and conditions of the Budapest Treaty.

Applicants provide attached to this paper a Declaration Re: Deposit of Microorganisms attesting to the deposit of the strain HPIV3 JS cp45 under the terms and conditions of the Budapest Treaty, and providing further assurances regarding availability of the strain to the public upon grant of a U.S. Patent. Applicants submit that the filing of this Declaration obviates this ground of rejection.

Rejection under 35 U.S.C. § 102

Claims 67, 73-75, 255 and 278 remain rejected under 35 U.S.C. § 102(b) as being anticipated by Murphy et al. WO '078. This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

The present claim 67 recites that the infectious, self-replicating, recombinant HPIV2 of the present invention comprises a "polyhexameric recombinant HPIV2 genome or antigenome." Applicants have previously argued that the Examiner bases this rejection on an assertion that the nature of the recombinant HPIV2 genome as "polyhexameric" is inherent to the virus.

The Examiner has not been persuaded by Applicants arguments to the contrary, at least in part because she interprets the disclosure in Kawano et al. (2001) at page 106, left paragraph, as establishing that HPIV2 efficiently replicates only when the total number of nucleotides in the

HPIV2 genome or antigenome obeys the "rule of six". Applicants submit that the Examiner has misunderstood the disclosure of the Kawano et al. (2001) paper.

The complete text in the paper is excerpted below:

> the previously reported hPIV2 genome length were not 6n length. Hence, at least three different RT±PCR clones of hPIV2 were sequenced, and one nucleotide deletion was found in 39-noncoding region of HN gene in previously reported hPIV2 sequence (data not shown). This result indicated the total number of nucleotides in the correct hPIV2 genome was a multiple of six. For SV, it was found that efficient replication of the genome only occurred when the total nucleotide numbers obey the "rule of six" (Calain and Roux, 1993). However, Murphy and Parks (1997) suggested that the genome of 6n length was a preference but not absolute requirement for SV5 replication. Although the full-length cDNA used for the rescue of rPIV2 was not 6n length (15,665 nt including genetic tag), infectious virus could be isolated, and the recombinant virus could efficiently replicate in various cells. The full-length cDNA has one nucleotide deletion in the 39-noncoding region of M gene. Nevertheless, the replication and transcription of rPIV2 showed the kinetics comparable to wtPIV2 (unpublished data). Thus, likewise SV5, hPIV2 does not appear to absolutely obey to the "rule of six," suggesting that 6n length genome has less significance in *Rubulavirus* than in *Respirovirus*.

The Examiner seems to have mistaken discussion about efficient replication of "SV" (*i.e.* Sendai Virus) for discussion about HPIV2. In this regard the Examiner should note that Kawano et al. (2001) observes that rPIV2 clones having a genome length that is not a multiple of six nucleotides replicates as efficiently as wild type HPIV2, and thus conclude that, "hPIV2 does not appear to absolutely obey to the "rule of six"," suggesting that 6n length genome has less significance in *Rubulavirus* than in *Respirovirus*.

Applicants accordingly reiterate their prior argument that

> while Murphy '078 shows experimental results demonstrating that replication of a minigenome using HPIV**3** replication signals at the 5' and 3' ends of the virus is highest if the length of the minigenome is a multiple of six nucleotides in length, the data also show significant replication occurs at lengths that are not multiples of six. See, Fig. 5B of the reference, at data points +1 and +3. Therefore, Murphy '078 teaches that a HPIV virus having a length that is not a multiple of

six nucleotides will replicate, although at a lower rate compared to a polyhexameric virus.

Thus, that HPIV2 should have a polyhexameric genome was not established as a fact at the time the present application was filed, and a polyhexameric genome or antigenome should not be considered an inherent property of a HPIV2 virus. Accordingly, Murphy '078 should not be taken to disclose a polyhexameric genome (or antigenome) as an inherent property of HPIV2, and the instant rejection should be withdrawn.

Rejection under 35 USC § 103(a)

Claim 76 is rejected under 35 USC § 103(a) as being unpatentable over Murphy WO '078 in view of Skiadopoulos et al. (1999). This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

Applicants submit that the combined references fail to establish *prima facie* obviousness of the claimed invention. In particular, the deficiencies of Murphy WO '078 to teach or suggest feature of the polyhexameric rHPIV2 genome or antigenome have been explained above. The Examiner cites Skiadopoulos et al. (1999) only for the disclosure of the particular *cp*45 mutations recited in claim 76. Skiadopoulos et al. (1999) does not remedy the fundamental deficiency of Murphy WO '078 and so the combination of these references fails to establish *prima facie* obviousness of the claimed invention. Accordingly, the instant rejection should be withdrawn.

Applicants submit that the pending application is in condition for allowance. The favorable actions of withdrawal of the standing rejections and allowance of the claims are requested.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Mark J. Nuell, Ph.D., Reg. No. 36,623, at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.14; particularly, extension of time fees.

Dated: August 20, 2009

Respectfully submitted,

By _____
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